REMARKS

The Office Action dated March 11, 2008 has been carefully considered. Claims 1-19, 23, 25 and 26 are pending. Claims 20-22 have been cancelled without prejudice. Applicant reserves the rights to prosecute the cancelled claims and subject matter in one or more related applications. Claims 1, 25 and 26 have been amended to specify that the drug layer in the claimed patch unit is a drug-in-matrix layer or a drug-in-adhesive layer. Claim 11 has been amended to specify that the permeation enhancing agent is used alone, *i.e.*, not admixed with acceptable carriers and the like. Support for these amendments can be found in the originally-filed application at, *e.g.*, page 3, line 34 to page 4, line 1; page 4, lines 12-13; and page 17, lines 28-29. It is believed that no new matter has been added.

Reconsideration and allowance of the present application in view of the following remarks are respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. § 103(a)

A. Claims 1-4, 7-19, 23 And 25-26 Are Patentable Over Pagedas In View of Benecke

The Examiner has rejected claims 1-4, 7-20, 22-23 and 25-26 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,221,384 to Pagedas ("Pagedas") in view of U.S. Patent No. 5,008,110 to Benecke *et al.* ("Benecke"). In particular, the Examiner directs Applicant's attention to the drawings, which allegedly show "the membrane with a border around it consisting of the backing layer." (Office Action, page 7.) Thus, the Examiner concludes that "[s]ince the drug of the dosage unit is confined to the membrane, one of ordinary skill in the art would determine that the border of the backing layer would comprise the adhesive material without drug admixed therein." *Id.* Further, with respect to claims 4, 10 and 11, the Examiner contends that Benecke supplements Pagedas with the drug, the softening agent, and the permeation enhancing agent recited in these claims and therefore rendering them obvious. The Examiner also finds unpersuasive Applicant's previous argument that Benecke teaches away from the presently claimed invention. (Office Action, page 7.) For the following reasons, Applicant respectfully disagrees.

Independent claims 1, 25, and 26, as amended, recite methods of delivering a drug (claims 1 and 25) or a narcotic analgesic (claim 26) through a patient's skin using a transdermal delivery system comprising a plurality of patch units. Each patch unit comprises a backing layer having one or more borders, a drug-in-matrix layer or a drug-in-adhesive layer comprising a drug disposed on the backing layer, and an adhesive layer. The borders of

the backing layer are free of any drug, and at least a portion of *the adhesive layer is disposed on the borders of the backing layer* (emphasis added). The plurality of patch units are connected to each other along one or more borders of the patch units; and each patch unit is defined by one or more lines of separation along the borders of the patch units. The method includes the steps of separating at least one patch unit from the transdermal delivery system along at least one line of separation; and applying at least one patch unit such that the drug layer makes contact with the skin.

Pagedas does not teach or suggest a patch unit wherein at least a portion of the adhesive layer is disposed on the borders of the backing layer, as recited in claims 1, 25 and 26. As shown in Fig. 3, a separate encapsulated drug layer 24 is disposed on the backing layer 28 (col. 3, lines 49-50) and a membrane 22 is disposed on the border of the backing layer. As shown in Fig. 3a, a membrane 22 is disposed on the entire backing layer 28. Thus, in neither Figure is an adhesive layer disposed on the border of the backing layer. Moreover, since the drug is microdispersed on the surface of the membrane 22 in Fig. 3a (col. 3, lines 50-52), the backing layer does not even have any border that is free from any drug, as recited in claims 1, 25 and 26.

In addition, Pagedas does not disclose or suggest a narcotic analgesic, a local anesthetic, a sedative, or a tranquilizer as recited in claim 1, buprenorphine as recited in claim 25, or a narcotic analgesic as recited in claim 26.

Accordingly, Applicant submits that Pagedas not only fails to disclose or suggest all the claim limitations of the presently claimed method which includes providing a transdermal delivery system, but teaches away from such method by requiring a membrane between the border of the backing layer and the adhesive layer.

Benecke does not remedy the deficiencies of Pagedas. First, unlike the presently claimed invention or Pagedas, Benecke is not even directed to a transdermal delivery system comprising *a plurality of patch units*. In particular, Benecke does not disclose or suggest a plurality of patch units that are connected to each other along one or more borders of the patch units, wherein each patch unit is defined by one or more lines of separation along the borders of the patch units, and the step of separating at least one patch unit from the transdermal delivery system along at least one line of separation, as required by the present claims.

Second, Benecke also does not teach or suggest a patch unit having a drug-in-matrix layer or a drug-in-adhesive layer disposed on a backing layer, as recited in the present claims.

In fact, Benecke is not directed to a drug-in-matrix type or a drug-in-adhesive type transdermal delivery system, as recited in the presently claimed methods, but rather a reservoir type transdermal delivery device (*see* Abstract). Moreover, in Benecke, the drug reservoir is not even disposed on the backing layer, as recited in claims 1, 25 and 26; rather, it is encapsulated within a hermetically-sealed compartment (*see e.g.*, Abstract; Figs. 2 and 6). For this reason, Applicant submits that Benecke teaches away from the presently claimed invention. Furthermore, the compartment in Benecke serves to prevent the drug formulation from contacting the adhesive positioned between the compartment and the backing layer (*see* Abstract); Pagedas, on the other hand, allows contact of the drug with the adhesive layer (*see e.g.*, Fig. 3a). For the above reasons, Applicant submits that one of ordinary skill in the art would not find motivation or a reasonable expectation of success to modify or combine the teachings of Pagedas and Benecke to obtain the presently claimed invention.

Accordingly, claim 1 and its dependent claims, and claims 25 and 26, are believed to be patentable over Pagedas in view of Benecke. Thus, withdrawal of this rejection and allowance of claims 1-4, 7-19, 23 and 25-26 are respectfully requested.

B. Claim 5 Is Patentable Over Pagedas In View Of Benecke And Further In View of Miranda

Claims 5 and 21 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Pagedas in view of Benecke and further in view of U.S. Patent No. 5,091,186 to Miranda *et al.* ("Miranda"). Specifically, the Examiner asserts that it would have been obvious to incorporate a rate limiting releasing agent into the drug layer or drug-in-matrix layer based on the teachings of Miranda (Office Action, page 6). For the following reasons, Applicant respectfully disagrees.

Claim 5 depends from claim 1 and further recites that the transdermal delivery system comprises a release limiting layer disposed on the drug layer. For the reasons discussed above in connection with claim 1, claim 5 is also believed to be patentable over Pagedas and Benecke.

Miranda does not cure the deficiencies of Pagedas and Benecke. Miranda, like Benecke, does not even disclose or suggest a transdermal delivery system comprising *a plurality of patch units* comprising a backing layer having one or more borders, wherein each patch unit is defined by one or more lines of separation along the borders of the patch units, and the step of separating at least one patch unit from the transdermal delivery system along at least one line of separation, as required by the present claims. Miranda also does not teach

or suggest a patch unit wherein at least a portion of the adhesive layer is disposed on the borders of the backing layer, wherein the borders are free of any drug, as recited in the present claims. Lastly, although Miranda teaches that a rate limiting agent may be incorporated in the transdermal delivery device, Miranda does not disclose or suggest a release limiting *layer* which is disposed on a drug layer, as recited in claim 5 (emphasis added).

Furthermore, one skilled in the art would not find motivation in Pagedas, Benecke, or Miranda to combine the teachings of these references to obtain the presently claimed invention, particularly where Benecke teaches away from a drug-in-matrix layer and a drug-in-adhesive layer disposed on a backing layer of the patch unit, and Pagedas and Miranda do not disclose or suggest an adhesive layer disposed on the borders of a backing layer, wherein the borders are free of any drug.

As such, claim 5 is believed to be patentable over Pagedas, Benecke and Miranda. Accordingly, the rejection is believed to be in error and should be withdrawn.

C. Claim 6 Is Patentable Over Pagedas In View Of Benecke And Further In View of Katz

Claims 6 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Pagedas in view of Benecke and further in view of U.S. Patent No. 5,028,435 to Katz *et al.* ("Katz"). Specifically, the Examiner stated that Katz discloses a transdermal patch comprising the encapsulation of the active drug in microcapsules (Office Action, page 8). For the following reasons, Applicant respectfully disagrees.

Claim 6 depends from claim 1 and further recites that the drug is encapsulated by microcapsules. For the reasons discussed above in connection with claim 1, claim 6 is also believed to be patentable over Pagedas and Benecke.

Katz does not cure the deficiencies of Pagedas and Benecke. Katz, like Benecke, also does not disclose or suggest a plurality of patch units wherein each patch unit is defined by one or more lines of separation along the borders of the patch units, and the step of separating at least one patch unit from the transdermal delivery system along at least one line of separation, as required by the present claims.

Moreover, the percutaneous enhancer in Katz is contained within polymeric particles dispersed through the matrix layer. Since claim 6, as amended, recites that the permeation enhancer is used alone, *i.e.*, not admixed with carriers, Applicant submits that Katz in fact teaches away from the presently claimed invention.

As such, claim 6 is believed to be patentable over Pagedas, Benecke, and Katz, and Applicant respectfully requests that the rejection be withdrawn.

CONCLUSION

Thus, as the claim rejections are believed to be overcome, the pending claims are believed to be in condition for allowance. Reconsideration and allowance of the present application are respectfully requested. An early notice to that effect would be appreciated. Should the Examiner not agree with Applicant's position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

Respectfully submitted,

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